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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,118	11/12/2003	Stephen C. Macevicz	55525-8045.US01	8171

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EXAMINER	
LU, FRANK WEI MIN	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,118	MACEVICZ, STEPHEN C.	
	Examiner	Art Unit	
	Frank W Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 23-32 is/are pending in the application.

4a) Of the above claim(s) 23-27 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 28-32 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission of RCE and the amendment filed on August 17, 2005 have been entered. The claims pending in this application are claims 28-32. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of amendment filed on August 17, 2005.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 32 recites the limitation "said first and second sequence tags" in the claims. There is insufficient antecedent basis for this limitation in the claim because there is no phrase "first and second sequence tags" in claim 28. Please clarify.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by New England Biolabs 96/97 Catalog (pages 19, 37, 108 and 109).

Regarding claim 28, New England Biolabs 96/97 Catalog teaches a pBR322 Pst I site primer (#1240) (see page 109). Since this pBR322 Pst I site primer taught by New England Biolabs 96/97 Catalog is 30 bases in length and contains two restriction sites wherein 5'-CCGG-3' is a Hpa I site and 5'-GCTA-3' is a Bfa I site and 2.0 A_{260} unit of the pBR322 Pst I site primer must contain more than one identical primers (see pages 19, 37, and 109), this catalog discloses that a plurality of oligonucleotides (ie., more than one identical pBR322 Pst I site primers), each said oligonucleotide containing first and second end segments from opposite ends of one such fragment wherein said first end segment consists of a first end sequence (ie., ATTGTTG), having 5 to 12 basepairs, immediately adjacent to a cleaved restriction site (ie., CCGG, a cleavable HpaI site), said second end segment consists of a second end sequence (ie., AGTAGTT), having 5 to 12 basepairs immediately adjacent (ie., 4 bp away) to a cleaved restriction site (ie., CTAG, a cleavable Bfa I site), and said first and second end sequences are ligated together (ie., by 16 nucleotides between the first end sequence and the second end sequence) wherein each end sequence contains the same number of basepairs (ie., 7 bp) and wherein each end sequence is unique as recited in claim 28. Although this catalog does not teach that a plurality of

oligonucleotides are derived from restriction fragments of a polynucleotide wherein each said oligonucleotide contains first and second end segments from opposite ends of one such restriction fragment as recited in claim 28, since that claim 28 is directed to a product and is not directed to a method of making a product, the patentability of claim 28 does not depend on how the product recited in claim 28 is made. It is known that the patentability of a product does not depend on its method of production. If the claim is a product-by-process claim, it is well established that even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Regarding claims 29-31, since claims 29-31 are directed to a method for making the product of claim 28, claims 29-31 are anticipated by New England Biolabs 96/97 Catalog.

Regarding claim 32, New England Biolabs 96/97 Catalog teaches that said plurality of includes a number of oligonucleotide (ie., identical multiple pBR322 Pst I site primers) having a size (ie., 30 bp) sufficient to contain with a probability of ninety-nine percent at least one copy of each of said pairs of sequence tags (ie., 14 bp). Although this catalog does not teach that at least one copy of said pairs of sequence tags is from each said restriction fragment of said polynucleotide as recited in claim 32, since that claim 32 is directed to a product and is not directed to a method of making a product, the patentability of claim 32 does not depend on how the product recited in claim 32 is made. It is known that the patentability of a product does not

depend on its method of production. If the claim is a product-by-process claim, it is well established that even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Therefore, New England Biolabs 96/97 Catalog teaches all limitations recited in claims 28-32.

7. Claims 28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Howard *et al.*, (BioTechniques, 7, 940-942, 1989).

Regarding claim 28, since Howard *et al.*, teach a 51 bp chemically synthesized polylinkers with different restriction sites (see Table 1 in page 940), Howard *et al.*, disclose that a plurality of oligonucleotides (ie., multiple identical chemically synthesized polylinkers taught by Howard *et al.*,), each oligonucleotide containing first and second end segments from opposite ends of one such fragment wherein said first end segment consists of a first end sequence (ie., GAATTC), having 5 to 12 basepairs, immediately adjacent to a cleaved restriction site (ie., Not I site), said second end segment consists of a second end sequence (ie., AAGCTT) having 5 to 12 basepairs, immediately adjacent to a cleaved restriction site (ie., Sac II site) and said first and second end sequences are ligated together wherein each end sequence contains the same number of basepairs (ie., 6 bp) and wherein each end sequence is unique as recited in claim 28. Although

Howard *et al.,* do not teach that a plurality of oligonucleotides are derived from restriction fragments of a polynucleotide wherein each said oligonucleotide contains first and second end segments from opposite ends of one such restriction fragment as recited in claim 28, since that claim 28 is directed to a product and is not directed to a method of making a product, the patentability of claim 28 does not depend on how the product recited in claim 28 is made. It is known that the patentability of a product does not depend on its method of production. If the claim is a product-by-process claim, it is well established that even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Regarding claims 29-31, since claims 29-31 are directed to a method for making the product of claim 28, claims 29-31 are anticipated by Howard *et al.*.

Regarding claim 32, Howard *et al.,* teach that said plurality includes a number of oligonucleotide (ie., multiple identical chemically synthesized polylinkers taught by Howard *et al.,*) having a size (ie., 51 bp) sufficient to contain with a probability of ninety-nine percent at least one copy of each of said pairs of sequence tags (ie., 12 bp). Although Howard *et al.,* do not teach that at least one copy of said pairs of sequence tags is from each said restriction fragment of said polynucleotide as recited in claim 32, since that claim 32 is directed to a product and is not directed to a method of making a product, the patentability of claim 32 does not depend on how the product recited in claim 32 is made. It is known that the patentability of a product does

not depend on its method of production. If the claim is a product-by-process claim, it is well established that even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Therefore, Howard *et al.,* teach all limitations recited in claims 28-32.

Response to Arguments

8. Applicant's arguments with respect to claims 28-32 have been considered but are moot in view of the new ground(s) of rejection. Although claims 28-32 in above rejections under 35 USC 102 are rejected using New England Biolabs 96/97 Catalog, since different parts of New England Biolabs 96/97 Catalog are used in the rejection, the rejections are the new ground(s) of rejection.

Conclusion

9. No claim is allowed.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30

(November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571)272-0745.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
Primary Examiner
October 27, 2005